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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,056	06/22/2001	Kenneth Kornman	MSA-023.01	6975
7590	12/01/2004		EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, PC ONE FINANCIAL CENTER BOSTON, MA 02111			WILDER, CYNTHIA B	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/888,056	KORNMAN ET AL.
	Examiner	Art Unit
	Cynthia B. Wilder, Ph.D.	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 May 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-7,9-23,26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,4-7,16-23,26 and 27 is/are rejected.
- 7) Claim(s) 3 and 9-15 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4, 6, 19, 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- (a) Claims 4, 6, 19 and 21 are indefinite for the limitations in parentheses because it cannot be determined if the limitations in parentheses are a part of the claims and if so, what the limitations are in reference to or if the limitations are a separate entity. Clarification is required.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 5, 7, 16, 17, 20, 22, 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Potter et al (US 5,780587, July 14, 1998). Regarding claims 1, 16, and 23, Potter et al teach a method for identifying a substance that is likely to prevent or diminish a specific biological response in a subject having an inflammatory disease-associated genotype, said method comprising the step of (a) observing in a test subject or immune cell of a test subject having an inflammatory disease-associated genotype, a biomarker; (b) contacting said test

subject or cell of said test substance with a test substance; (c) observing again in said test subject or cell said biomarker and (d) administering an inducer to the test subject or cells prior to or concomitant with observing said biomarker; wherein a change in said biomarker from an inflammatory disease associated phenotype to a non-inflammatory disease associated phenotype identifies a test substance or cell that is likely to prevent or diminish or reduce the specific biological response in a subject having said inflammatory disease-associated genotype (abstract and col. 2, line 55 to col. 3, line 36 and col. col. 8, line 55 to col. 12, line 57 and col. 17, line 3 to col. 18, line 44).

Regarding claims 2 and 17, Potter et al teach the embodiments of claims 1 and 17, wherein said subject has at least one inflammatory disease associated with IL-1 receptor (abstract and col. 2, line 55 to col. 3, line 36 and col. col. 8, line 55 to col. 12, line 57 and col. 17, line 3 to col. 18, line 44).

Regarding claims 5 and 20, Potter et al teach the embodiments of claims 1 and 16, wherein said inflammatory disease-associated genotype is associated with a predisposition to a disease, wherein said disease is Alzheimer's disease (abstract).

Regarding claims 7 and 22, Potter et al teach the embodiments of claims 2 and 16, wherein said biomarker is selected from the group consisting of blood level of soluble IL-1 receptors or large-scale protein level analysis (col. 2, line 55 to col. 3, line 36 and col. 8, line 55 to col. 12, line 57 and col. 17, line 3 to col. 18, line 44 and examples).

Regarding claims 26 and 27, Potter et al teach the embodiment of claim 16, wherein said inducer is IL-1 (col. 18, line 15 to line 44). Therefore, Potter et al meets the limitations of claims 1, 2, 5, 7, 16, 17, 20, 22, 23 and 26 of the instant invention.

***Conclusion***

5. Claims 1, 2, 4-7, 16, 17-23, 26 and 27 are rejected. Claims 3, 9-15 are objected to because they depend from rejected claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to [cynthia.wilder@uspto.gov](mailto:cynthia.wilder@uspto.gov). Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
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